REMARKS/ARGUMENTS

Claims 1, 2 and 15 are pending in the instant application. Claims 3 through 14 and 16 through 18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Claim 1 has been amended, support for which may be found at page 9, lines 30 through 31, and elsewhere within applicant's specification, as originally filed. Claims 5 and 7 have been amended to correct minor informalities.

The Examiner has rejected claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961. The rejection of applicant's claims is respectfully traversed. Reconsideration and favorable action is respectfully solicited in view of the following.

The Examiner has rejected claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961. The Examiner is of the view that:

> Yoon teaches a hollow suturing needle (60) comprising an internal cavity wherein a drug to be dispensed can be released by holes extending through walls communicating with the lumen and sealed in the suture needle by attachment of suture material which does not extend the length of the lumen, and wherein the fluid may be an antibiotic (Column 7, proximate lines 4-20).
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> Yoon fails to teach a compressed gas residing between the fluid and the non-hollow portion or seal. Hubbard teaches a device having an internal cavity therein comprising: a proximal end (18), a distal end (16), a point on the distal end (fig. 2), an opening at or in the proximity of the distal end, and a non-hollow portion or seal at or adjacent to the proximal end (16); wherein the internal cavity is in fluid communication with said opening at one end

> and terminates at said non-hollow portion or seal at the other end (fig. 1); a fluid (M) residing within the internal cavity; and a compressed gas (G) residing between the fluid (M) and the non-hollow portion or seal (18), (Columns 3-4, proximate lines 60-75 and 1-5 respectively), in order to provide a disposable fluid dispensing device that is simple to manufacture and provides effective ejection of medicine from the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon with the pressurized gas ejection mechanism of Hubbard in order to provide a disposable needle that is simple to manufacture and provides effective ejection of medicine from the device.
>
> The combination of Yoon and Hubbard fails to teach wherein the suture is formed of metal. McGregor teaches a suture needle wherein the needle is formed of metal in order to provide a material having sufficient strength to perform procedures without breakage or deformation. It would have been obvious to one of ordinary skill in the art a the time the invention was made to modify the combination of Yoon and Hubbard with a needle made of metal for non-endoscopic procedures such as suturing skin in order to provide a needle with sufficient strength to perform procedures without breakage or deformation. ...
>
> It appears the product disclosed by the combination of Yoon, Hubbard and McGregor would be the same and would perform equally well as that claimed; especially since both applicant's product and the prior art have the same final shape and structure of a needle being formed from tubing, i.e. having a channel there through

Yoon et al., U.S. Patent No. 4,981,149, proposes bioabsorbable suture devices for use in endoscopic surgery. The proposed devices include a suture needle made of bioabsorbable material for pulling a length of suture material through bodily tissue, allowing the suture needle to be inadvertently or intentionally left in the tissue, and a suture needle having a length of suture material attached thereto with a contractible loop or passage at the proximal end of the suture material to allow the suture needle to be passed therethrough, the loop or passage contracting to clamp or grip the suture material to function similar to a conventional tied suture knot.

Hubbard et al., U.S. Patent No. 3,308,820, proposes a disposable medicinal hypodermic syringe that is said to have utility in the administration of a liquid medicament. The disposable medicinal hypodermic syringe is a single unitary structure having a sealed vial unit containing a charge of liquid medicine or other liquid to be injected into the patient's tissue under sealed gas pressure; a hollow injection needle or cannula; and a mechanically stabilized, transparent and flexibly compressible aspiration sleeve or tube unit sealingly applied between the vial unit and the cannula, for checking by vacuum inducement against the possibility that the cannula has penetrated a blood vessel, prior to the discharge of the medicine under gas pressure into muscular tissue. The syringe may also be used for intravenous injection.

McGregor et al., U.S. Patent No. 5,649,961, proposes a process for the manufacture of suture needles and, more particularly, a process for enhancing the physical strength of the suture needles through an expedient cold-working or cold-forming procedure. Also disclosed is the provision of a physically strengthened suture needle, particularly a surgical suture needle possessing a curvilinear configuration, wherein the cross-sectional configuration of the needle is cold-formed into varying shapes in order to produce a needle having superior physical characteristics and strengths imparted thereto through the inventive process. The needles are essentially cold formed. The process includes the aspect of imparting to straight metal rods, which are preferably constituted from stainless steel, manufacturing steps which include sharpening one end of rod severed segments so as to form the needle tip, thereafter curving the needle with the metal still being in a relatively ductile state, and subjecting the needle to a cold forming process to produce varying cross-sectional shapes along the length of the needle.

It is respectfully submitted that to approach applicant's claimed invention would require that, at a minimum, the suture needle of Yoon et al., which is

produced from a bioabsorbable material, be replaced with one produced from metal tubing, a modification that would destroy the stated object and function of the Yoon et al. invention. As stated at col. 3, lines 13-19 of Yoon et al.

> [It is a]n object of the present invention is to construct a suture needle ... of a bioabsorbable material such that, should the suture needle be dropped or lost during endoscopic surgery, open surgery is not required to remove the needle.

As is well-settled under the law, if a reference is cited that requires some modification in order to meet the terms of applicant's claimed invention and that modification would destroy the purpose or function of the invention disclosed in the relied-upon reference, one of ordinary skill in the art would find no reason to make the proposed modification. The Federal Circuit has consistently held that when a rejection is based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in that reference, such a proposed modification is not proper and a prima facie case of obviousness cannot be properly made. The Federal Circuit noted in In re Gordon, at 221 USPQ 1127, 733 F.2d 902, that "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." It is respectfully submitted that the lack of technical motivation for making the modifications necessary to arrive at applicant's claimed invention is evidence that the suggestion for the modification could not have come from the references themselves.

Moreover, as may be appreciated, a careful review of the relied upon references reveals that nowhere is a suture needle having a yielding moment and an internal cavity therein comprising a proximal end, a distal end, a point on the distal end, an opening at or in the proximity of the distal end, and a non-hollow portion or seal at or adjacent to the proximal end; the internal cavity having a cross-

sectional area and being in fluid communication with said opening at one end and terminates at said non-hollow portion or seal at the other end; a fluid residing within the internal cavity; and a compressed gas residing between the fluid and the non-hollow portion or seal, wherein the suture needle is produced from metal tubing, the suture needle possessing a non-linear relationship between the cross-sectional area of the internal cavity and the yielding moment, fairly taught or suggested. In view thereof, the applicant respectfully requests that the rejection of claims 1, 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., U.S. Patent No. 4,981,149, in view of Hubbard et al., U.S. Patent No. 3,308,820 and further in view of McGregor et al., U.S. Patent No. 5,649,961, be removed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(13925).

It is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

Respectfully submitted,

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